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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,203	12/31/2001	Alan Garen	OCR-679B.US	9075

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EXAMINER	
HELMS, LARRY RONALD	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,203	GAREN ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- Th MAILING DATE of this communication appears on the cov r she t with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14 and 17-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a composition comprising a mutant form of factor VII which binds tissue factor and has reduced blood coagulation relative to wild type and a Fc domain. In view of this the combination of Thorpe et al (US Patent 5,877,289) in view of Berkner et al (US Patent 5,861,374) and Wang et al (PNAS 96:1627-1632, 1999) reads on the claim. Thorpe teach immunoconjugates and modified tissue factors and conjugates to binding agents (see column 10) and Berkner teach mutant forms of Factor VII and Wang teach immunoconjugates comprising a dimer of Fc and scFv molecules. The references result in rendering the invention obvious because it would have been obvious to combine the teachings to produce the claimed invention. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6-8, 21-22, 46-47, drawn to composition of an immunoconjugate of an Fc and a mutant form of factor VII.

Group II, claim(s) 1-8, 21-22, 46-47, drawn to composition of an immunoconjugate of an Fc and a mutant form of factor VII and a second molecule of an immunoconjugate.

Group III, claim(s) 9-11, 14, 19, 23-24, 48, in part and claim 13, 17 drawn to a method of treating cancer with an immunoconjugate of a mutant factor VII and an Fc.

Group IV, claim(s) 9-12, 14, 18-19, 23-24, 48, in part and claim 13, 17 drawn to a method of treating cancer with an immunoconjugate of a mutant factor VII and an Fc and a second immunoconjugate.

Group V, claim(s) 9-11, 14, 23-24, 48 in part and 35, drawn to a method of treating arthritis with an immunoconjugate of a mutant factor VII and an Fc.

Group VI, claim(s) 9-11, 14, 23-24, 37, 48 in part and 36, 49, drawn to a method of treating macular degeneration with an immunoconjugate of a mutant factor VII and an Fc.

Group VII, claim(s) 9-11, 14, 23-24, 48 in part and claim 38, drawn to a method of treating arteriosclerosis with an immunoconjugate of a mutant factor VII and an Fc.

Group VIII, claim(s) 9-12, 14, 23-24, in part and claim 35 drawn to a method of treating arthritis with an immunoconjugate of a mutant factor VII and an Fc and a second immunoconjugate.

Group IX, claim(s) 9-12, 14, 23-24, in part and claim 13 drawn to a method of treating cancer with an immunoconjugate of a mutant factor VII and an Fc and a second immunoconjugate.

Group X, claim(s) 9-12, 14, 23-24, 37, in part and claim 36, drawn to a method of treating macular degeneration with an immunoconjugate of a mutant factor VII and an Fc and a second immunoconjugate.

Group XI, claim(s) 9-12, 14, 23-24, in part and claim 38, drawn to a method of treating arteriosclerosis with an immunoconjugate of a mutant factor VII and an Fc and a second immunoconjugate.

Group XII, claim(s) 20, 50-53, drawn to a method of treating cancer by administering a vector.

Group XIII, claim(s) 25-26, 31-32, drawn to a composition comprising an immunoconjugate of an effector domain and a targeting domain that binds tumors and does not comprise an scFv or a VH.

Group XIV, claim(s) 27-28, 33-34 in part, and claim 29 drawn to a method of treating cancer by administering an immunoconjugate of an effector domain and a targeting domain that binds tumors and does not comprise an scFv or a VH.

Group XV, claim(s) 27-28, 33-34 in part, drawn to a method of treating arthritis by administering an immunoconjugate of an effector domain and a targeting domain that binds tumors and does not comprise an scFv or a VH.

Group XVI, claim(s) 27-28, 33-34 in part, drawn to a method of treating macular degeneration by administering an immunoconjugate of an effector domain and a targeting domain that binds tumors and does not comprise an scFv or a VH.

Group XVII, claim(s) 27-28, 33-34 in part, drawn to a method of treating arteriosclerosis by administering an immunoconjugate of an effector domain and a targeting domain that binds tumors and does not comprise an scFv or a VH.

Group XVIII, claim(s) 39-45 drawn to DNA and vectors.

Group XIX, claim(s) 50, 52-53 in part, drawn to a method of treating arthritis by administering an vector.

Group XX, claim(s) 50, 52-53 in part, drawn to a method of treating macular degeneration by administering an vector.

Group XXI, claim(s) 50, 52-53 in part, drawn to a method of treating arteriosclerosis by administering an vector.

2. The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Thorpe et al (US Patent 5,877,289) in view of Berkner et al (US Patent 5,861,374) and Wang et al (PNAS 96:1627-1632, 1999) the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I-II, XIII, and XVIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The composition of Group I is an immunoconjugate and the composition of Group II comprises two immunoconjugates. Group XIII is also distinct because it does not have a scFv or a VH, whereas Groups I-II have to have a scFv and a VH. Group

XVIII is a polynucleotide which is different in structure from the proteins of Groups I-II and VIII. The polynucleotide is made by nucleic acid synthesis while the proteins are made by translation of RNA. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-II, VIII, and XVIII are patentably distinct.

The methods of Inventions III-XII, XIV-XVII, XIX-XXI differ in the method objectives, method steps and parameters and in the reagents used. The methods recite different objectives such as treatment of cancer, arthritis, etc. In addition the methods are distinct because some require one immunoconjugate while others require two. In addition, methods XIX-XXI and XII require administration of a vector which is not required in the other methods. Thus Inventions III-XII, XIV-XVII, XIX-XXI differ in the method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions I-II and III-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immunoconjugate of Group I can be used in any one of the materially different methods of Groups III, and VVII and the immunoconjugates of Group II can be used in any one of the materially different methods of Groups IV, VIII-XI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

4. Claims 9, 27, 48, 50 link(s) inventions III-XI, XIV-XVII, XIX-XXI, XII . The restriction requirement is subject to the nonallowance of the linking claim(s), claims 9., 27, 48, 50 . Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In

the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.